

WHAT IS CLAIMED:

- 1 1. A method for increasing likelihood of effectiveness of an ErbB antagonist
2 cancer treatment, which method comprises administering a cancer treating dose of the ErbB
3 antagonist to a subject, wherein an *erbB* gene in tumor cells in a tissue sample from the subject has
4 been found to be amplified.
- 1 2. The method according to claim 1, wherein the ErbB is a HER2 protein.
- 1 3. The method according to claim 2, wherein the cancer is breast cancer.
- 1 4. The method according to claim 3, wherein the subject has been found to have
2 a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.
- 1 5. The method according to claim 1, wherein the ErbB antagonist is an anti-ErbB
2 antibody.
- 1 6. The method according to claim 5, wherein the ErbB is HER2, and the
2 antibody is recombinant human monoclonal antibody (rhuMAb) 4D5.
- 1 7. The method according to claim 1 wherein the *erbB* gene amplification is
2 detected by detecting fluorescence of a fluorescent-labeled nucleic acid probe hybridized to the gene.

1 8. The method according to claim 7, wherein the *erbB* gene is a *her2* gene..

1 9. The method according to claim 1, which further comprises administering a
2 cancer treating dose of a chemotherapeutic drug.

1 10. The method according to claim 9, wherein the ErbB is HER2 and the
2 chemotherapeutic drug is a taxoid.

1 11. The method according to claim 1, wherein the likelihood of effectiveness
2 increases by about 30%.

1 12. A method for increasing likelihood of effectiveness of an anti-HER2 antibody
2 to treat cancer, which method comprises administering a cancer treating dose of the anti-HER2
3 antibody to the subject, wherein a *her2* gene in tumor cells in a tissue sample from the subject have
4 been found to be amplified.

1 13. The method according to claim 12, wherein the subject has been found to have
2 a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.

1 14. The method according to claim 12, which further comprises administering a
2 cancer treating dose of a taxoid.

1 15. A pharmaceutical package comprising:
2 (a) a container comprising an ErbB antagonist for treating a cancer; and
3 (b) instructions to administer the ErbB antagonist to a subject if an *erbB* gene in
4 tumor cells in a tissue sample from the subject is amplified.

1 16. The package of claim 15, wherein the ErbB antagonist is an antibody.

1 17. The package of claim 16, wherein the antibody is an anti-HER2 antibody.

1 18. The package of claim 17, wherein the anti-HER2 antibody is rhuMAb 4D5
2 (Herceptin®).

1 19. The package of claim 15, wherein the instructions further comprise directions
2 to administer a chemotherapeutic drug in combination with the ErbB antagonist.

1 20. The package of claim 19, wherein the chemotherapeutic drug is a taxoid.

1 21. A method for identifying a patient disposed to respond favorably to an ErbB
2 antagonist for treating cancer, which method comprises detecting *erbB* gene amplification in tumor
3 cells in a tissue sample from the patient.

Sub
B1

- 1 22. The method according to claim 21, wherein the subject has been found to have
2 a 0 or 1+ score by immunohistochemistry on a formaldehyde-fixed tissue sample.
- 1 23. The method according to claim 21, wherein the erbB is *her2*.

100-27500-100-28600